Izjava EU o skladnosti
EU Declaration of conformity

proizvajalca | of the manufacturer

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SRN: DE-MF-000010680

S tem na lastno odgovornost izjavljamo, da je navedena naprava:

Vrsta naprave	**Mala centrifuga**
Ime	**EBA 200**
Osnovni UDI-DI	**040506740100249W**
GMDN	**47154**
Razvrstitev	**Medicinski pripomoček, razred IIa (Priloga VIII, poglavje III, pravilo 3)**
Skladno z	**Uredbo (EU) 2017/745 Priloga IX**
Vključeni priglašeni organ	**mdc medical device certification GmbH; CE 0483 Kriegerstraße 6; 70191 Stuttgart; Germany**

vključno s priloženim priborom, za katerega je bila ocenjena skladnost, kar je navedeno na seznamu pribora v pripadajoči tehnični dokumentaciji, ki je skladna z zadevnimi določili Uredbe (EU) 2017/745 o medicinskih pripomočkih.

Namen uporabe

Centrifuga **EBA 200 (MD)** je medicinski pripomoček skladno z Uredbo o medicinskih pripomočkih (EU) 2017/745.
Naprava je namenjena za ločevanje sestavin polne človeške krvi ali sestavin človeške krvi.
Uporabnik lahko spremenljive fizične parametre nastavi v mejah, ki jih dopušča naprava.

Centrifugo sme uporabljati samo usposobljeno osebje v zaprtih laboratorijih.

We hereby declare under our responsibility that the designated device:

Type of device	**Small centrifuges**
Name	**EBA 200**
Basic UDI-DI	**040506740100249W**
GMDN	**47154**
Classification	**Medical Device, class IIa (Annex VIII, Chapter III, Rule 3)**
according to	**Regulation (EU) 2017/745 Annex IX**
Involved Notified Body	**mdc medical device certification GmbH; CE 0483 Kriegerstraße 6; 70191 Stuttgart; Germany**

and its accessories, which are listed in the related technical documentation and whose conformity has been assessed together with the device, complies with the relevant provisions of the Regulation (EU) 2017/745 on medical devices.

Intended use

The **EBA 200 (MD)** centrifuge is a medical device according to the Regulation on Medical Devices (EU) 2017/745.
The device is used to separate whole blood or blood components of human origin into its component parts.
The user can set each of the variable physical parameters within the limits set by the device.

The centrifuge may only be used by qualified personnel in closed laboratories.

Naprava je skladna tudi z zadevnimi določili naslednjih evropskih direktiv, uredb in standardov

- Direktiva o strojih 2006/42/ES
- Direktiva o elektromagnetni združljivosti 2014/30/EU
- Direktiva o nizkonapetostnih napravah 2014/35/EU
- „Direktiva RoHS“ 2011/65/ES (brez udeležbe priglašenega organa)
- Uredba o registraciji, evalvaciji, avtorizaciji in omejevanju kemikalij (REACH) (ES) 1907/2006 (brez udeležbe priglašenega organa)

Uporabljeni standardi:
Glejte seznam uporabljenih standardov, ki je del tehnične dokumentacije.

The device also complies to the applicable provisions of the following European directives, ordinances and standards

- 2006/42/EC “Directive on machinery”
- 2014/30/EU “EMC Directive”
- 2014/35/EU „Low Voltage Directive“
- 2011/65/EC “RoHS Directive” (without involvement of a notified body)
- (EC) 1907/2006 „Regulation on REACH“ (without involvement of a notified body)

Standards applied:
See the list of applied standards that forms part of the technical documentation.

Tuttlingen, 25.09.2025

Ralf Ledda
Izvršni direktor, Chief Executive Officer

CE 0483

Ta izjava o skladnosti velja od 25.09.2025 do 25. 08. 2027

This declaration of conformity is valid from 25.09.2025 until 25.08.2027